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SECTION 5 - 510(K) SUMMARY

AVIAFIT™ DEVICE

510(k) Number K_____

Applicant's Name:

Company name:	FlowMedic Ltd.
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Tel.:	+972 (4) 627-5559
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E-mail:	info@flowmedic.com

Contact Person:

Contact Name:	Ahava Stein
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Date Prepared:

Date: June 12, 2011

Name of the device:

AviaFit™ Device

Trade or proprietary name, if applicable:

AviaFit™ Device

Common or usual name:

Compressible Limb Sleeve

Establishment Registration No.:

3005003051

Classification Name:

Compressible Limb Sleeve (21 CFR 870.5800, Product Code JOW)

Classification:

FDA has classified Compressible Limb Sleeve devices as Class II devices (product code JOW), which are reviewed by the Cardiovascular Devices Panel.

Predicate Device:

The AviaFit™ Device is substantially equivalent to the originally cleared AviaFit™ Device (also manufactured by FlowMedic Ltd. and the subject of 510(k) document no. K071744) and the DVTcare CA5 device (manufactured by Doctor's Orders Inc. and the subject of 510(k) document no. K061125).

Device Description:

The FlowMedic AviaFit™ is a battery operated portable device integrating a patented mechanical intermittent compression technology to improve blood circulation in the lower limbs and reduce the risk of deep vein thrombosis, edema and leg discomfort during limited mobility conditions. The device is comprised of an actuator and a strap and is externally mounted on the calf.

The anatomical concave shaped control unit is connected to the leg strap and applied to the calf. Using an innovative low power consumption mechanism, the system tugs and releases the leg strap placed around the calf muscle, thus exerting intermittent cycles of external pressure build-up on the tissue, and a subsequent release, thus aiding venous return. Strap tug and release are controlled by a system of gears, springs, a motor and integrated microprocessor contained in the plastic control unit.

The device mimics the muscle activity during walking by acting sequentially in cycles of an active interval of exerting pressure on the muscle, thus augmenting blood flow, followed by a loose state for a period of time, allowing blood flow to return to the limb.

Intended Use / Indication for Use:

The AviaFit™ Device is intended for use to help prevent the onset of DVT in patients by stimulating blood flow in the legs (simulating muscle contractions). Furthermore, the unit can be used as an aid in the prophylaxis for DVT by persons traveling, or those expecting to be stationary for long periods of time (> 4 hours). This device can also be used to aid in the prevention of DVT, enhance blood circulation, diminish post-operative pain and

swelling, reduce wound healing time, and aid in the treatment and healing of: stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency, and reduction of edema in the lower limbs.

Comparison of Technological Characteristics with the predicate device:

The technological characteristics of the AviaFit™ device are similar to the technological characteristics of the predicate devices including mechanism of action (e.g., compression to simulate muscle contraction), pressure range of compression, compression time and cycle time, treatment site, indicators, power requirements, etc.

Non-Clinical Performance Data and Performance Standards

The performance tests performed on the original, cleared and identical AviaFit™ device verified that the operating characteristics and performance of the device are in accordance with its specifications.

Clinical Performance Tests:

Not Applicable.

Conclusions Drawn from Non-Clinical and Clinical Tests:

The non-clinical tests demonstrated that the AviaFit™ device meets its design and performance specifications.

Substantial Equivalence:

The AviaFit™ device has the same intended use as the DVTcare CA5 device. Furthermore, the AviaFit™ device has the same technological characteristics, (i.e., same mechanism of action, and similar design and specifications) as the originally cleared AviaFit™ device and the DVTcare CA5 predicate device. The differences in the new device do not raise new issues of safety or effectiveness. In conclusion, the modified AviaFit™ device is substantially equivalent to the predicate devices and therefore, may be cleared for marketing in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FlowMedic Ltd.
c/o Ms. Ahava Stein
Regulatory Affairs Consulting
15 Alon Hatavor Street
Industrial Area Caesarea
Caesarea, 38900
ISRAEL

SEP 16 2011

Re: K111720
AviaFit™ Device
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: June 14, 2011
Received: June 20, 2011

Dear Ms. Stein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 - INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K111720

Device Name: AviaFit™ Device

Indications for use:

The AviaFit™ Device is intended for use to help prevent the onset of DVT in patients by stimulating blood flow in the legs (simulating muscle contractions). Furthermore, the unit can be used as an aid in the prophylaxis for DVT by persons traveling, or those expecting to be stationary for long periods of time (> 4 hours). This device can also be used to aid in the prevention of DVT, enhance blood circulation, diminish post-operative pain and swelling, reduce wound healing time, and aid in the treatment and healing of: stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency, and reduction of edema in the lower limbs.

Prescription Use √ OR Over-The-Counter Use_____.
(Per 21 C.F.R. 801 Subpart D) (Optional Format Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111720